

# The Product Safety Engineering Newsletter

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Vol. 2, No. 3 September 2006

## President's Message

Henry Benitez, President, Product Safety Engineering Society

First of all, I wish to invite all of you to the 3<sup>rd</sup> annual IEEE Product Safety Engineering Society Symposium this October 23-24 in Irvine, California. The technical program has remained excellent. I thank Richard Nute for his heroic efforts in putting together high quality programs for the first three years of this Society. The symposium is evolving to include product compliance for safety, electromagnetic compatibility and environmental compliance aspects. The symposium attendance and number of exhibitors is expected to increase significantly for years to come.



It is nearing time to renew IEEE PSES membership. The success of our young Society depends on increased membership, successful symposia and financial viability. We are moving in the right direction with our symposiums. We need to continue to increase our membership. I suggest

**The  
Product  
Safety  
Engineering  
Newsletter**

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- <http://www.ieee-pses.org/newsletters.html>
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that members promote membership enrollment to colleagues so that we can develop as much synergy as possible. Financial viability is becoming a greater challenge. Restructure of the IEEE infrastructure charges resulted in greater impact to the smaller societies. PSES being the smallest society was impacted the most. Representatives for the smaller societies and greatest impacted societies will meet in October to address this situation.

We look forward to another great symposium and look forward to seeing you and our respective colleagues in California!

Sincerely

Henry Benitez  
IEEE Product Safety Engineering Society  
h.benitez@ieee.org

## Get the *eDJ*!

**New section continues with this issue.**

Our new peer-reviewed papers section, the *eDJ*, continues with this issue. “*eDJ*” stands for “*e*lectronically *D*istributed, *J*ournal-quality” papers plus more.

The papers are those originally submitted for the Journal on Product Safety Engineering, whose launch has been postponed until we develop a stronger paper flow. These papers promote, recognize and archive work that advances the theory and practice of product safety engineering.

The first *eDJ* paper was published in our June 2006 issue. Both it and our paper in this issue address basic issues within the medical device industry that have some broader applications to other industries. Read both and “get the *eDJ*” for your job!

## IEEE PSES Needs Volunteers

**Please contact any Board Member on page two and  
find out how you can help!**

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## People Looking To Start Chapters

Want to start a chapter? Send your contact information to Stefan Mozar and it will be included in the chapter news. If you have chapter updates please send them to Stefan Mozar as well at [s.mozar@ieee.org](mailto:s.mozar@ieee.org).

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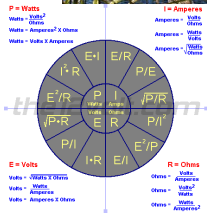
# Explore Your Practical Side



Ohm's Law



$$\mathcal{E} = IR$$



$0.2 < \mu < 0.3$  where  $\mu =$  coefficient of friction

Faraday's Law summarizes the ways voltage can be generated.

Changing magnetic flux  $\frac{d\Phi}{dt} = 4 \text{ mT/s}$   
 $N = 10$  turns  
 $V_{\text{gen}} = -N \frac{d\Phi}{dt} = -10 \times 4 = -40 \text{ volts}$

Changing magnetic field  $\frac{dB}{dt} = 0.2 \text{ mT/s}$   
 $N = 3$  turns  
 $V_{\text{gen}} = -N \frac{d\Phi}{dt} = -3 \times 0.2 \times 0.2 = -0.12 \text{ volts}$

Rotating coil in magnetic field  $\frac{d\Phi}{dt} = 0.2 \text{ mT/s}$   
 $N = 20$  turns  
 $V_{\text{gen}} = -N \frac{d\Phi}{dt} = -20 \times 0.2 \times 0.2 = -0.8 \text{ volts}$



Kirchoff's Law

Put Theory into Practice.... Designing Safe Products for your World



## 2006 IEEE Symposium on Product Safety & Compliance Engineering



Explore the practical side of Engineering in an interactive experience on the latest advancements in product safety engineering. Understand how theory is put into practice through standards, regulations and codes used in design of products.

Join your colleagues in a forum for exchanging ideas, practical experiences, work experiences and business cards.

Target audience includes Technicians, Educators, Administrative personnel, Engineers, Consultants, Local, State and Federal regulators, National standards committee members, International standards committee members



Sponsored by the IEEE Product Safety Engineering Society  
**Irvine, California** **23 – 24 October 2006**  
<http://www.ieee-pses.org/symposium>

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# Standardization: Is the U.S. Losing a Competitive Edge?

Are we facing an acute shortage of knowledgeable standards development workers?

The latest annual report developed by the Council for Harmonization of Electrotechnical Standards of the Nations of the Americas (CANENA) warns that a reduction in technical resources available for voluntary standardization is reaching critical proportions.

Why? Experts say there are several reasons: (1) mergers, acquisitions, and budget reductions correlate with lower company investment in standards development and harmonization; (2) the number of U.S. government participants and technical experts who traditionally have contributed to the development of private sector voluntary standards has declined sharply in the past eight years; (3) consortia standardization methods, much different from traditional committee work, are growing in popularity; and (4) standardization is not a top priority among schools of engineering—and the academic sector is not preparing engineering students to support or replace those engineers who are currently involved in standardization projects.

There is no quantitative evidence that the overall level of technical expertise and participation in International Electrotechnical Commission (IEC) standards development is shrinking. Some areas see shrinkage, others see growth. The disparity is related to market segment. The deregulation of utilities in certain states in the U.S., for example, has led to fewer numbers of experts participating. On the other hand new standards development activities, such as the work of IEC Technical Committee 111 on Environmental Aspects, is generating plenty of international technical interest.

The U.S. is a little different story. Over the years, there has been a reduction of technical experts supplied by NEMA member companies. People retire and are not replaced. Larger companies that once had corporate staff participating in many NEMA committees have eliminated that function. There seems to be a lack of long-term commitment to technical support. Proponents say that standards education is one way to turn the ship around. Very few colleges and universities, either in the U.S. or Europe, offer courses on standards education in their engineering or business curricula. The Catholic University of America in Washington, D.C., is one of the very few which offers a course in standards education. The university also has a Center on Global Standards Analysis. But a recent national survey of 100 universities in the U.S. found that only two additional schools offer standards courses.

Other regions, especially Asia, pay much more attention to standards education. The President of South Korea, for instance, has spoken about the importance of standards education as a marketing strategy for his country. Today, there are 40 universities and 6000 students in South Korea involved in standards education. It may be the most impressive program in the world. China and Japan are beginning to see the strategic value of standards and are also introducing standards subject matter into university curricula.

In May 2005, the China Software Industry held a conference in Beijing to discuss information

Continued on Page 9

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Membership subscriptions are annualized to, and expire on, 31 December 2007.  
Pay full or half-year rate depending upon the date of receipt by the IEEE.

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All prices quoted in U.S. dollars

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Years in current position \_\_\_\_\_ Years of practice since graduation \_\_\_\_\_

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USA-only include 5-digit billing zip code

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**NOTE: In order for us to process your application, you must complete and return this form to:**

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Piscataway, NJ 08855-6804 USA**

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Signature \_\_\_\_\_ Date \_\_\_\_\_

**APPLICATION MUST BE SIGNED**





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technology standards. The conference program clearly outlined the significance of technology standards to China's future:

“Whoever controls the power of standard making and has its technology as the leading standard, commands the initiative of the market. [The] technology standard has become an important means of global economic competition, directly influencing the competitiveness of an industry, a region, or a country.”

Center on Global Standards Analysis Chairman Don Purcell says, “If countries in Asia, such as Korea, China, Japan, and India, intend to spend considerable resources to educate their best and brightest engineering students in the field of standardization, these countries will gain a clear and distinct competitive advantage in future negotiations of complex standards intended for application in the global marketplace. In short, the economic and technological leadership of countries in the Americas is at risk.”

Europe, too, may be beginning to grasp the benefits of standards education. The IEC has recently distributed to its members two lecture series on a compact disk, developed by Purcell, to support university curricula covering standardization and its impact on business, industry, and engineering. IEC national members are also being encouraged to push for inclusion of standards in university programs.

In addition to the need for standards education, CEOs and corporate managers must become increasingly aware that standards development is a strategic business issue that has direct impact on new product development. CEOs with technical background understand this more and usually provide human resources and funding for standards development work.

Standards education should also be taught in business schools, schools that produce many of our business leaders. A recent NEMA leadership satisfaction survey indicates that CEOs need to understand better the value of NEMA membership in terms of tangible and quantifiable benefits to their companies. Standards education, an awareness of the importance of standards to the company's bottom line, and increased investment in technical resources are good first steps if the U.S. is to reverse an unfortunate trend and retool the engine of standardization.

In December 2005, the United States Standards Strategy established standards education as a national priority:

*“Establish standards education as a high priority within the United States private, public, and academic sectors. Education programs covering the development and implementation of standards need to become a high priority within the United States. These programs must focus on the needs of leaders and top executives, those who participate in the development of standards, university and college students, and other interested parties.”*

Although private, public, and academic sectors in the United States are now reviewing alternatives that might reflect this priority, the essential question is whether the United States and other countries in the Americas can remain competitive in global markets if significant standardization initiatives and comprehensive standards education programs have been established in other parts of the world, and there is no competitive response from the Americas.

*This article is reprinted with permission from the May 15, 2006 issue of electroindustry, published by the National Association of Electrical Manufacturers.*

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Letter to the editor  
I endorse the following Candidates in the current IEEE elections. Ted Freeman

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Division III  
William H. Tranter

Division V  
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Tony Robertson  
Manager – Customer Training

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- Network with technical experts at local events and industry conferences.
- Receive discounts on Society conferences and symposiums registration fees.
- Participate in education and career development.
- Address product safety engineering as an applied science.
- Have access to a virtual community forum for safety engineers and technical professionals.
- Promotion and coordination of Product Safety Engineering activities with multiple IEEE Societies.
- Provide outreach to interested engineers, students and professionals.
- Have access to Society Publications.



**IEEE**



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Membership: The society ID for renewal or application is “043-0431”. Yearly society fee is US \$35.

# Back to Basics: Life and the Hipot Failure

## Back to Basics

The following article begins an occasional PSEN department featuring the fundamental tools, techniques, and principles underlying the work of the product safety engineer.

## Life and the Hipot Failure

by Andrew Delonno

It seems that it never fails, five o'clock on a Friday and it's the last test for the day before the weekend. The tester is turned on, the test button is pressed then suddenly that horrible sound. It's the buzz of the hipot as the red light dimly glows, "FAIL." So much for leaving at five o'clock.

Many product safety engineers have had similar experiences, maybe not at five o'clock on a Friday, but the sinking feeling is the same nonetheless. A hipot failure is, by far, the worst test to fail. You see no smoke, no dramatic flames, no high temperatures. The only thing the engineer has is the tester saying, "FAIL." Seasoned engineers and technicians know that troubleshooting a hipot failure is usually difficult, but with a systematic approach even a relatively new engineer stands a good chance of finding the failure. This article will provide an approach that should help find a failure within a circuit.

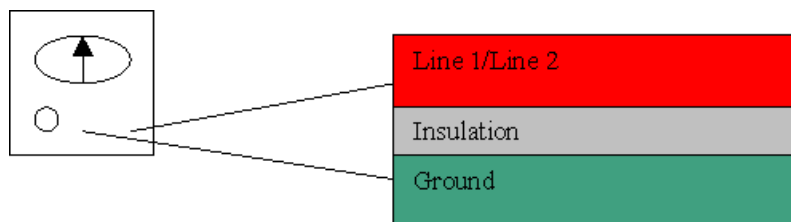


Figure 1: A basic diagram of the test intent.

First, what is a hipot failure? The best way to understand the failure is to understand the intent of the test. During the test, a higher than normal voltage is applied between two parts of the Equipment Under Test (EUT). A basic hipot test would be between L1/L2 and Ground (Figure 1). The critical insulation systems in the EUT are required to have a certain insulation type such as basic insulation or double insulation as defined in the end product safety standard. The hipot test is evaluating the insulation to determine if the insulation is:

- 1) Adequate for normal or reasonably foreseeable abnormal operation OR
- 2) Has been damaged or weakened to an extent where it is failed or could fail.

The damage could be the result of a test imposed on the system, such as a component failure during qualification testing; or it could be used to determine if there has been an assembly error, such as chaffing of a wire during system assembly.

The hipot tester (often referred to as U1) monitors leakage current between the two test

points, and if the leakage current exceeds a set value, then it indicates a failure. It is important to realize that the leakage current in the hipot test is not the same as the system leakage current during the operation of the system at normal line voltages. Rather, it is the leakage current imposed by the hipot test itself. The leakage current setting on the hipot is not normally specified in the standards and really is not critical in a real hipot failure. This is true since in a hipot failure there is a catastrophic “avalanche” breakdown of the insulation system. This breakdown would occur if the hipot was set for 5 mA or 15 mA, since a relatively large current flows when the insulation-undergoing test conducts as a result of the hipot voltage placed across it (Figure 2).

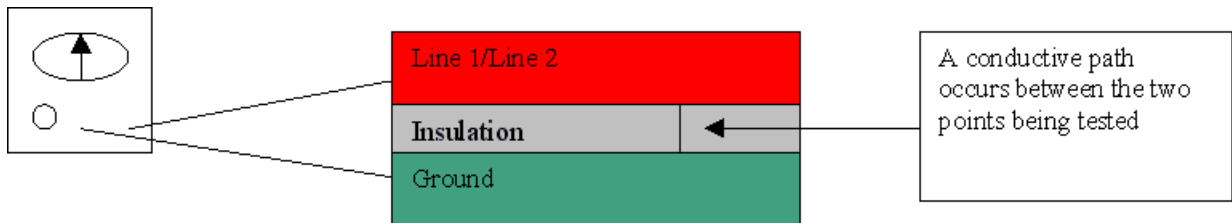
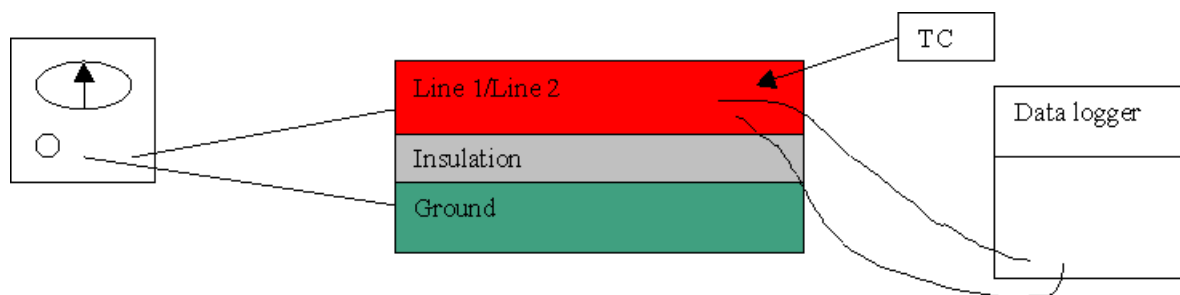


Figure 2: What happens in a breakdown.

What could fool a leakage current sensor circuit in a hipot tester?

- 1) A component intentionally conducting between the two points under test. Certain surge suppression components may be conducting between the test points. If these components are present, then they need to be removed from the circuit. These are the only components that can be removed prior to hipot, according to most standards.



- 2) A breakdown of insulation that you are not intending to test and that is not part of the equipment being tested. This could be through thermocouples (TCs) as an example (Figure 3). During the certification process, TCs are strategically placed within the EUT and could provide unintentional electrical paths for a hipot test voltage. The leakage could be into the data logger (not usually good for the data logger input circuits) or the TC insulation could be breaking down to ground well away from the circuits under test. The solution is to isolate the TCs and possibly remove them from the EUT for the hipot test.
- 3) Make sure the EUT is not on a conductive surface. The conductive surface may be causing paths for either leakage or other components to conduct back. The other

Continued on Page 14

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components would be items such as TCs or other probes that may be present during the qualification of the EUT.

- 4) Can the hipot tester successfully ramp up to set voltage? If the failure occurs at a low voltage (around 500 V or less), then there is a very good electrical breach of the insulation system. If it reaches a higher voltage and “hovers,” then it is likely that something is leaking excessively. These two bits of information may help the technician later on and should be noted. This may help the technician determine where to start looking and which steps below are important.

After all of the above items have been eliminated as possible sources of false readings, then there is a good possibility that there is actually a hipot failure within the circuits that are under test. Where can one start when trouble shooting this failure? Most hipot testers shut off as soon as the failure is detected, and if the observers are lucky there may be a “pop” sound from the discharge just before the hipot shuts down. Hipot tester tripping is a great feature for the safety of the test personnel, but it makes life difficult when there is a failure and the same personnel are trying to troubleshoot. Where do they start when evaluating the circuit?

- 5) Start with some basics. If the technician is testing line to ground then try L1 to ground and L2/N to ground. Testing the halves of the circuit may point the technician to a specific area quickly. More often than not it will provide little information since both halves fail. But depending on the hipot failure, it could save tremendous time and is worth the small effort needed to perform this step.
- 6) If there is a noise, then get another person to operate the hipot tester and try to see or hear the location of the breakdown. If the failure can be seen or heard in the general area of the breakdown, then the technician may determine where the failure is occurring. Don't rely too heavily on this being successful; it is basically left to luck.
- 7) If the breakdown cannot be isolated by sound or sight, then start with the core circuitry. The core circuitry is the minimum circuit present with all circuit breakers open, fuses pulled, switches in the circuit off, cables disconnected and contactors/relays open. If the hipot fails now, there is one of two possibilities: The core circuit is failing or there is something that was missed from the first four points above.
- 8) With the core circuitry passing, start adding in the circuits one at a time by flipping on switches, re-inserting fuses, closing circuit breakers, reconnecting cables and closing contactors/relays. At some point during the “adding in” process, the hipot will indicate, “FAIL.” This tells the technician that this specific “added in” circuit has a suspected hipot failure in it. Again, this circuit may be introducing one of two possibilities: The added in circuit has a hipot failure or there is something that was missed from the first four points above. Assuming that the failure is a hipot failure, then the technician should make sure that this is the only failure in the EUT. Disconnect the failing circuit from the core circuitry and continue to test the remaining circuits by adding them to the core circuit one at a time until they are all tested. Assuming that they all pass, add every circuit to the core circuit except for the failed circuit and re-test. If it fails then the technician has probably missed something from steps 1 through 4. Assuming that it passes, add in the failing circuit to all of the other circuits with the core circuit. The

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tester should indicate fail. If it does not, then you have not located the hipot failure and are probably being fooled by something in one of the first 4 points above.

- 9) This is where the fun starts. The technician already knows that he or she cannot hear or see the failure. If possible, some investigation may help locate the failure. Reviewing circuit board trace diagrams, looking for insulation failure burn marks, or looking for areas where clearances may be violated (such as excessive lead lengths on a printed wiring board assembly) may point the technician toward the failure. Any damage, sagging or other deterioration of electrical supports could also lead to breaching the clearance distances.
- 10) If the investigation of the circuit fails to turn up the elusive failure, then a possible final option exists. This option will help you find the failure, but it will also destroy the sample. In certain hipots, the shutdown circuitry can be disabled. This shutdown circuitry is important for personnel safety for all people in the test area, and disabling this circuitry should only be performed by persons very familiar with hipot testing. Extreme caution must be used during this step to prevent accidental exposure to the high output voltage from the hipot tester. If the personnel doing the troubleshooting are not familiar with these safety procedures then they should not be performing this step.

After you disable the shutdown circuit begin the hipot test watching the suspect circuit. It should breakdown and spark continuously. When this happens the tester is continually breaking down the insulation under test. If the insulation is a plastic or other solid insulator then the damage is very likely permanent and the EUT's circuit in question will be destroyed. If the breakdown is with air (because of a clearance problem) then the air will renew once the hipot is turned off. Once the clearance is corrected, it is possible that the EUT will not have permanent damage; however, this assessment will need to be performed on a case-by-case basis by a fully qualified engineer. The good news is that the technician now knows where the failure is and this information will help the engineering design team figure out how to fix the design to eliminate the hipot failure point. Before moving on from here, please remember to re-engage the auto shutdown circuitry in the default settings of the hipot.

Any experienced technician or product safety engineer will likely agree that hipot test failures are the most difficult of all of the product safety tests to isolate and describe. Going through the steps outlined above will help, in a systematic way, to avoid a false hipot failure within an EUT and will help confirm the location of any real failures. Knowledge on the location of the real failure is critical for the development team to develop a correction and allow the design to proceed through the product safety certification process. Without this approach, trial and error and a lot of extra time could be spent in locating a hipot failure.

*Andrew Delonno is product safety engineer with Agilent Technologies. He holds a BS in Electrical Engineering and has 15 years of international product safety experience. During his career he has worked for two different NRTLs, and he has several years of manufacturing experience.*

Sponsored by the IEEE Product Safety Engineering Society  
22-23 October 2007 near Denver, Colorado

## Call for Papers, Workshops, and Tutorials

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The IEEE Product Safety Engineering Society seeks original, unpublished papers and tutorials on all aspects of product safety and compliance engineering including, but are not limited to:

- **Products:** Consumer, medical, computer (IT), test and measurement, power supplies, telecommunication, industrial control, electric tools, home appliances, cellular and wireless, etc.
- **Safety Subjects:** Electrical, mechanical, fire, thermal, chemical, optical, software, functional, reliability, etc.
- **Components:** Grounding, insulation, opto-couplers, capacitors, transformers, current-limiters, fuses, power line filters, ferrite, environmental, electromagnetic emissions, electromagnetic immunity, regulatory, etc.
- **Certification:** Product safety, electromagnetic emissions, electromagnetic immunity, environmental, processes, safety testing, regulatory, etc.
- **Standards activities:** Development, interpretations, status, interpretations, country requirements, etc.
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- **Environmental:** RoHS, WEEE, EuP (Energy-using Products), Energy Star, Packaging Directives, REACH (Chemical), CeC, etc.

## Technical Paper Formats

Papers	Informal e-paper, workshop, or tutorial (e-presentation)	Formal e-paper, workshop, or tutorial	
		(e-publication version)	(e-presentation version)
Format:	Presentation (typically PowerPoint)	IEEE Xplore® PDF	Presentation (typically PowerPoint)
Acceptance document:	Draft e-presentation	Draft e-paper	none
Acceptance review:	Suitability review	Formal peer review	none
Proceedings CD:	No	Yes	No
Symposium CD:	Yes	No	Yes
Presentations:	20, 40, or 60 minutes	n/a	20, 40, or 60 minutes
Workshops and Tutorials	2 or more hours	n/a	2 or more hours
Media:	Personal laptop or symposium-provided computer	n/a	Personal laptop or symposium-provided computer
Presentation mode:	Video projector	n/a	Video projector

## Author's Schedule

Intent to present and topic (e-mail) April 29, 2007  
Draft e-paper June 1, 2007  
Notification of Acceptance July 6, 2007  
Complete e-paper August 17, 2007



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## 2007 Call For Symposium Papers continued

**Formal and informal papers and presentations:** A formal paper is prepared according to IEEE publication standards and is peer-reviewed. Formal e-papers are published as the official proceedings of the Symposium. A formal paper is accompanied by an e-presentation version of the paper.

An informal paper is an e-presentation only (usually in PowerPoint), and is reviewed by Symposium staff for suitability. E-presentations are published, but are not included as official proceedings.

Workshops and tutorials are also available. A workshop or tutorial is a hosted longer time slot with either a single speaker (tutorial) or multiple speakers (workshop) on related topics.

Both formal and informal presentations may include demonstrations, visual aids, animations, pictures, video, etc., which are highly encouraged.

**Paper acceptance:** Acceptance of a formal paper, informal paper, workshop, or tutorial is based on the draft e-paper or e-presentation. Drafts of formal e-papers are peer-reviewed by select members of the IEEE Product Safety Engineering Society. Acceptance is based on:

Importance of Topic: Does the subject matter have direct significance to the safety community and/or any aspects of product safety engineering?

Technical Sophistication and Depth: Does the paper, workshop, or tutorial present information that is of a significant contribution, advancement, application or refinement in the state of the art? Does the presentation expose the reader to a higher knowledge level than currently available from other sources?

Readability, Clarity and Presentation: Is the objective of the submission clearly defined? Is the material written in a clear and concise fashion, in proper English, and with topics presented in a logical and organized manner?

Novelty and Originality: Does the paper propose a new and unique aspect of product safety engineering, or clarify or expand on an existing premise from a unique point of view?

Drafts of informal papers (e-presentations) are reviewed by Symposium staff for suitability of the subject in context of the topics listed elsewhere in this Call for Papers.

If the draft e-paper is accepted, the author or presenter and organizers must pre-register for the symposium no later than August 24, 2007. Failure to pre-register by the due date will be cause for the paper to be withdrawn from being presented and published in the conference proceedings.

**Paper format:** Formal e-paper must be prepared and submitted in IEEE Xplore® PDF format. See <http://www.ieee.org/confpubcenter> for details on the submission format. Paper format can be checked by the IEEE web-based tool to at <http://216.228.1.34/pdfexpress/log.asp>.

E-presentations, both formal and informal, usually are in PowerPoint for presentation, and converted to PDF for publication. An e-presentation should include both the IEEE logo and the PSES logo on the opening and closing pages.

**Paper schedule:** Prospective authors, workshop organizers, and tutorial organizers should submit an "intent to present" e-mail (or e-mail attachment) describing the title, topic, objective, synopsis of the paper, expected duration of the presentation, and the type of paper, i.e., formal paper, informal paper, tutorial, or workshop. The "intent to present" is used for preliminary organization of the technical program, and to provide some initial feedback to the author on the paper and its position in the technical program. The "intent to present" does not commit the author or organizer to the paper or session. However, the "intent to present" will be taken as a strong indication that the paper or session will take place; the symposium will hold a place for the paper pending the draft e-paper and acceptance.

Receipt of the draft e-paper is taken as a commitment to present the paper at the Symposium. The Symposium schedule will be developed after receipt of all e-presentations.

Prospective authors are encouraged to submit before the due dates.

### **Presentation:**

All papers and presentations must be orally presented at the Symposium by the author or by his designated presenter.

### **Paper submittal:**

All communications, including "intent to present," draft e-paper, and completed e-paper should be sent to the Chairman of the Technical Program, Richard Nute, [richn@ieee.org](mailto:richn@ieee.org)

TBD

Chairman, Technical Program 2007 IEEE PSES Symposium

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# News and Notes

## Society

### **Product safety self-declaration proposal remains under consideration by U.S.-OSHA**

The previous *PSEN* issue reported that the U.S. Occupational Safety and Health Administration (OSHA) had posted in the *Federal Register* a public notice and request for information and comments regarding a proposal to allow IT manufacturers to bypass OSHA-mandated Nationally Recognized Testing Laboratories (NRTLs) and self-certify that their products meet safety standards. Deadline for comments was February 13, 2006. The matter has been included in the current OSHA Regulatory Agenda under Regulatory Identification Number 1218-AC21, with review of comments scheduled to be completed during October 2006.

### **“WHO-IS-IN-WHAT” project delayed but forthcoming**

As reported in the previous issue, the *PSEN* wants to facilitate networking among members, and was to have sent all society members a brief survey by e-mail. *PSEN* apologizes for the delay—the survey should be out soon. It will simply gather data from participants as to involvement in groups such as standards committees, national committees, etc. If the response level is adequate, *PSEN* will publish a listing of “WHO-IS-IN-WHAT.”

### **IEEE Member-Get-A-Member program wraps up**

From September 1, 2005 through August 15, 2006 the IEEE offered members a \$5 bounty in the form of a dues credit for each new member signed up. Hopefully the program was effective; the IEEE Membership Development office has not responded to *PSEN* requests for information as to results.

## What's new

### **Draft North American appliance safety standard nearly completed**

A two-day Technical Harmonization Committee meeting of CANENA was held in Washington, DC on August 2–3, and is probably the group's last face-to-face meeting. Remaining work on the tri-national 60335-1 standard is expected to be completed via teleconferencing. Time goals are for the draft to be entirely completed by late 2006 and the standard published by all three SDOs in early 2008.

### **PSES to approach academia**

The March 2006 *PSEN* noted that the PSES is developing a letter to go to the deans of engineering schools, inviting participation in the PSES. At last report, the letter remains under development.

### **ANSI to continue university outreach program**

The American National Standards Institute has announced its intent to continue the

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University Outreach pilot program launched in autumn 2005. Intended to provide the future workforce with a knowledge of standards, the program gives participating university faculty and students access to a wide range of standards and related documents, including the full collection of ISO standards and select IEC standards. ANSI also offers two basic courses on standards and conformity assessment at [www.standardslearn.org](http://www.standardslearn.org).

**Notes**

• **Volunteers Needed as Editors** Lingfeng Chen has resigned from the News & Notes Column. We need volunteers for this column. Please contact Gary Weidner if you are interested. He can be reached at [gweidner@ieee.org](mailto:gweidner@ieee.org).

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# EDITORIAL

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## The Cutting Board Syndrome

Along with watching for trends, the application of “common sense” is one of the fundamental tools that have served humans well for thousands of years. After all, where would we be without common sense?

The elegant simplicity of common-sense reasoning is usually so reliable that it can lull us into overconfidence. The logical flow that proceeds so smoothly sometimes hides pitfalls that can lead to faulty conclusions. If a faulty conclusion relates to, for example, how one should go about doing a chore, the consequences are likely to be minor. On the other hand, if common sense leads to a faulty conclusion in the product safety arena, the result may be injuries or significant economic costs.

Here are instances where common sense may have gone astray:

***In regulating medicine***—According to *Business Week* magazine, “When new drugs to treat life-threatening heart rhythms came on the market in the 1980s, the medical community made a logical leap. If the medicine worked in serious cases, doctors reasoned, then it must also work in cases of mild irregular rhythms, which are far more common. [Common sense.] The drugs quickly became the standard of care for these milder cases—even though they had never been tested for those conditions. Scientists finally performed a rigorous clinical trial later that decade... The results showed that, far from saving lives, the treatment was killing thousands of people every year.”

***In regulating transportation***—The 1974 federal speed limit of 55 miles per hour (mph) was legislated to save gasoline during an Arab oil embargo. When the oil shortage eventually dropped out of the picture, proponents of the speed limit said that it should be maintained in order to save lives, since it clearly was safer than higher speed limits. [Common sense.] However, the 55 mph federal speed limit was repealed in 1995. According to the *Wall Street Journal*, 31 states have since raised their speed limits to more than 70 mph, yet the National Highway Safety Administration reports that the rate of injuries per mile traveled was lower in 2005 than at any time since the Interstate Highway System was built 50 years ago.

***In regulating food processing***—A decade or two ago, the U.S. Department of Agriculture (USDA) urged cooks and food processors to cut foods on non-porous surfaces, typically plastic. The thinking was that, unlike porous wood surfaces, plastic would give bacteria less chance of escaping rigorous cleaning. Only later did microbiologists conduct studies to compare the germ retention of the two surfaces. To their surprise, the researchers found that after minimal cleaning, wood cutting boards were home to far less bacteria than thoroughly washed plastic cutting boards. When questioned about this, a USDA spokesperson responded that the agency had based its recommendations on “common sense.”

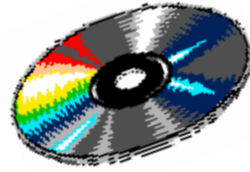
While there is debate about the reasons for the results described above, the inference we need to draw is that those involved in product safety should, whenever feasible, test their

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Continued on Page 24

## 2004 / 2005 IEEE-PSE Symposium

### CD Purchasing Information



SYMPOSIUM PAPERS ON CD:

The Product Safety Engineering Society continues to offer the 2004 IEEE PSES records for sale. The cost for the CD is \$35 plus shipping and handling for IEEE members; \$50 plus shipping and handling for non-IEEE members. At this time, check or money orders are the means for payment. Please provide the following information:

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Longmont, CO 80504  
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## New PSES Members since Jan 1, 2006 Through- October 12.

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KOREA  
DENMARK  
ARGENTINA

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“common sense” conclusions. Failure to do so can result in the “cutting board syndrome.”

Development of product safety standards is an area where the cutting board syndrome pops up periodically. A person or committee experienced in the principles of product safety decides, with flawless logic (common sense) that if a product does not incorporate feature A and feature B, unsafe condition C is likely to occur. Sometimes a person having practical experience with the product comes along and says, “There’s no question about the logic of the requirement, but actually in this type of product, the anticipated unsafe condition is extremely unlikely to occur because...” Try to find ways to test your reasoning!

**We are looking for  
Product Safety  
Articles!**

Please send proposals for articles to:

Gary Weidner  
Editor, IEEE PSES PSE Newsletter  
GW Technical Services Inc.  
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phone = 563-557-0717  
fax = 563-557-0725  
e-mail = [gweidner@ieee.org](mailto:gweidner@ieee.org)



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# The *eDJ*

A Peer-Reviewed Publication  
of the  
IEEE Product Safety Engineering Society

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**Mike Sherman**

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**Carl Schmuland**

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## The *eDJ*

A Peer-Reviewed Publication of the Product Safety Engineering Society

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### *From the eDJ Editor's Desk*

October 6, 2006

Dear Fellow Product Safety Engineering Professionals,

It seems at times that we live and die by the standards to which we design and evaluate our products. Some of us even spend a portion of our lives helping to write these standards, one benefit of which is an intimate understanding of the history and reasoning behind the various requirements.

The second issue of *The eDJ* brings you such an intimate understanding of the new edition of IEC 60601-1, the basic electrical safety standard for the medical device industry. The author, Charles Sidebottom of Medtronic, has spent much of his last 10 years bringing this third edition to fruition as the Secretary of IEC subcommittee 62A.

Those of you who work in the medical device industry will find this immediately useful as you get up to speed on the new edition. Those of us who work outside the industry will find the third edition's ideas of risk management, "essential performance," and "means of protection" to be useful lenses through which to view our work.

My personal and public thanks go out to Charles for his willingness, as an "old hand," to take the time to pass on some of his accumulated wisdom and insight. Our profession is still young and small enough that such sharing is essential to our ability to effectively do our jobs—protecting the users of our products.

Get the eDJ!

Mike Sherman  
eDJ Editor  
1-952-361-8140 work phone  
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# The New IEC 60601—The “bible” Rewritten

Charles Sidebottom, Secretary, IEC /SC 62A

**Abstract—** For more than 30 years, IEC 60601-1 has been one of the most widely recognized standards for demonstrating the safety of medical electrical equipment. The IEC 60601 family of standards has long been recognized by regulatory agencies in Europe, North America and Asia as establishing conformance with various regulatory requirements.

The third edition of IEC 60601-1 was published in December 2005.

This article describes how this edition enhances patient safety by integrating risk management throughout the very fabric of the standard, with compliance now requiring manufacturers to implement a formal risk management system conforming to ISO 14971.

The article also discusses an expansion of the scope to formally address essential performance as well as basic safety; to extend the standard beyond equipment that is only used “under medical supervision”; and to embrace equipment intended for “compensation or alleviation of disease, injury or disability” as well as that used in the “diagnosis, treatment, or monitoring of a patient.”

**Index Terms—**biomedical engineering, biomedical equipment, biomedical equipment safety, risk analysis

## I. INTRODUCTION

EVERY journey begins with a single step. For the newly appointed secretary of IEC Subcommittee 62A, that first formal step was taken in Cape Town, South Africa on November 20, 1996 when the subcommittee accepted the secretariat’s work plan for developing a third edition of IEC 60601-1. The third edition represented a major overhaul of IEC 60601 family of medical electrical equipment safety standards. First published in 1977, IEC 60601-1 underwent a major revision in 1988 and was amended in 1991 and 1995. During the intervening eighteen years, IEC 60601-1 had become the “bible” of electromedical equipment safety and the parent standard for over fifty particular device standards ranging from diagnostic electrocardiographs to electron accelerators used in radiotherapy.

The journey toward the third edition actually began a few years before, when the Subcommittee published the second edition of a technical report designated IEC 60513, *Fundamental aspects of safety standards for medical electrical equipment*. IEC 60513 sets out the philosophy and guiding principles that underlies all the work on the IEC 60601 family of standards. First published in 1976, IEC 60513 anticipated that:

- there would be separate equipment standards for “safety” and “performance”;
- safety matters would be covered by a parent standard (IEC 60601-1) and by a series of part 2 standards for particular types of electromedical equipment; and
- performance requirements would be covered by

a separate series of part 3 standards.

These principles guided the development of the first and second editions of IEC 60601-1, which is often referred to as the “general standard” or just the “bible.”

In the early 1990s, the subcommittee began work on a second amendment to the 1988 edition of IEC 60601-1 to address safety concerns embodied in the European Medical Device Directive. As IEC rules allow for only two amendments to any standard before a new edition must be developed, the subcommittee began planning for a third edition of the general standard by revising IEC 60513.

Because requirements for particular types of electromedical equipment are contained in particular (part 2) standards, the general standard does not need to change as rapidly as the particular standards in order to keep pace with new devices. In fact, stability on the part of the general standard is highly desirable so the particular standards have a firm base on which to build. However, as technology advances, the general standard must evolve to keep abreast of the state of the art in safety principles. Knowing that this process would take several years to complete, the subcommittee planned to begin work on the third edition almost as soon as the last amendment was published.

Published in 1994, the second edition of IEC 60513 anticipated a major overhaul of the bible and set out the key principles that would direct the work on the new edition. Five of the key principles described in the second edition of IEC 60513 are:

- the concept of “safety” will be broadened from the basic safety considerations in the first and second editions of IEC 60601-1 to include essential performance matters (Application of this principle led to a change in the title of the standard from “Medical electrical equipment, Part 1: General requirements for safety” in the second edition, to “Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.”);
- the pass/fail test criteria that have worked well for the first and second editions will be retained;
- provision is made for assessing the adequacy of the design process when this is the only practical method of assessing the safety of certain technologies (Application of this principle is one of the factors leading to introduction of a general requirement to establish a formal risk management process.);
- further harmonization with the basic safety standards developed by other IEC and ISO committees will be pursued; and
- where possible, an attempt will be made to align with the safety requirements that had been developed for information technology (IT) equipment and embodied in IEC 60950-1, *Information technology equipment - Safety - Part 1: General requirements*.

The plan approved in Cape Town in 1996 anticipated that 93 months would be required to develop, approve and publish the new “bible.” During the intervening years, over 150 experts from seventeen countries have contributed to the project. The project schedule slipped 17 months because the first voting document was narrowly defeated. However, the project was finally completed with the publication of the third edition of IEC 60601-1 in December 2005.

Continued on Page 28

## II. Changes to the Scope of the Third Edition

During the process of developing the third edition, the scope of the general standard was significantly modified and expanded. The first major change came in 1999, when the subcommittee resolved a long-standing debate about what many considered an unnecessary limitation in the scope of the standard. At a meeting in London, the subcommittee agreed to remove the phrase “under medical supervision” from the definition of medical electrical equipment. This change resolved the issue about whether the standard applied to equipment that met all the other characteristics of medical electrical equipment but was not intended to be used in a hospital, clinical or other location under the supervision of a medically trained professional. The automatic external defibrillators (AEDs) now so common in airports and other public spaces are a prime example. They clearly fulfill all the other characteristics of medical electrical equipment, but it can be persuasively argued that they are not intended to be used under medical supervision. Under the revised scope of the third edition, there is no question that AEDs are covered by IEC 60601-1.

The removal of “under medical supervision” also resolved many of the long-standing questions regarding equipment intended primarily for home use including devices considered in some markets to be personal hygiene equipment. If a device meets all of the characterizes in the definition of medical electrical equipment, it can now be considered within the scope of IEC 60601-1 regardless of where it is intended to be used and by whom.<sup>1</sup>

The second major change in scope came in 2003 when the subcommittee agreed to a proposal from France to add “or compensation or alleviation of disease, injury or disability” to the definition of medical electrical equipment. Historically, medical electrical equipment was limited to devices intended by their manufacturer to “diagnose, treat or monitor a patient.” During the debate on this proposal, it was noted that a strict interpretation of the scope of the second edition excludes certain patient handling and support equipment that are used in medical practice on patients and are not covered in the scope of the ISO Technical Committee dealing with aids for the disabled except that some models may be intended for both domains of use. The second edition definition of medical electrical equipment excludes devices such as electrically operated patient hoists which are not used in diagnosis, treatment, or

monitoring the patient, even though they have applied parts. To exclude aids for the disabled would leave a large hole in the standard’s coverage. Domestic equipment standards assume that the user is able bodied and can rely on the let-go reflex for voltages below approximately 25 Vac and 60 Vdc. This is not necessarily the case for disabled users due to their disability. A number of other standards, such as ISO 10535, *Hoists for the transfer of disabled persons – Requirements and test methods*, for patient lifting equipment, refer to IEC 60601-1 for electrical safety requirements and so for IEC 60601-1 to exclude this equipment would be a contradiction. This equipment does not monitor, diagnose or treat the patient, but the patient is still unable to get clear of a shock hazard, just as a patient under “therapy.”

## III. Structure of the Third Edition

One of the most contentious questions debated during the development of the third edition was the basic numbering structure of the document. The second edition maintained the basic organization of the 1977 standard. This resulted in a considerable number of clauses and subclauses being marked as “not used” and new material being added to the end of clauses, subclauses and lists. In addition, the new work item proposal for the third edition called for a radical reshaping of the standard with the general standard being divided into a series of separate documents. In the end, the subcommittee agreed to a proposal from Germany to keep the general standard as a single document (part 1) but reorganized the existing sections so they became subclauses with major clauses generally corresponding to the numbered sections of the second edition. Germany’s rationale for proposing this approach was that reducing the number of main clauses and aligning them with the old sections makes the structure easy to memorize. Should changes become necessary, only the numbering of the affected clause needs to be adjusted. The numbering of all other clauses can remain unchanged.

The structure of the IEC 60601 family based on the third edition of IEC 60601-1 is shown in Figure 1.

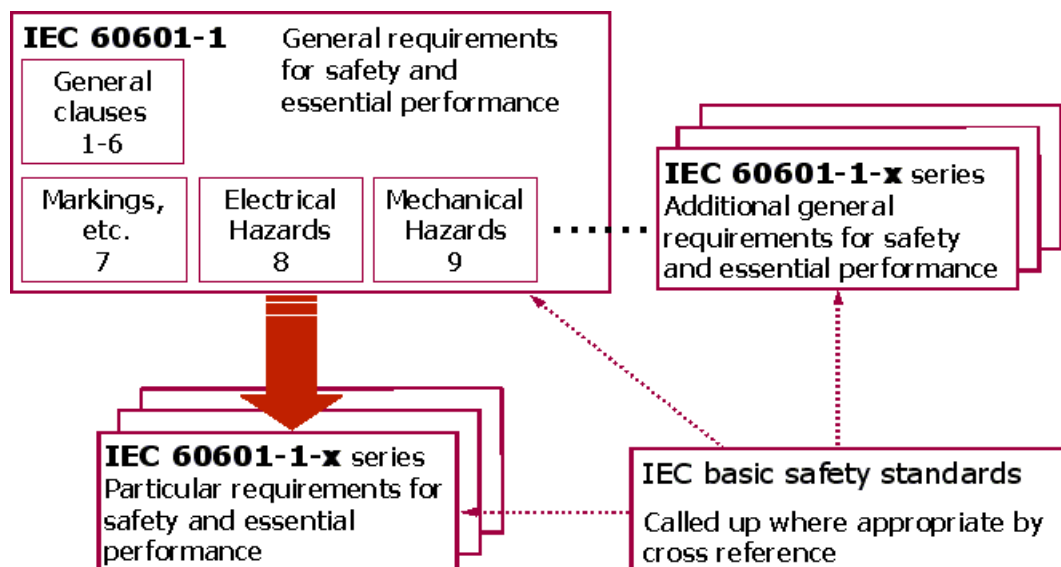


Fig. 1. Structure of the IEC 60601 family based on the third edition of IEC 60601-1

In the third edition, Clauses 1 through 6 cover common aspects such as general requirements, requirements for testing, and classification. This material largely corresponds to that contained in Section One of the second edition.

The general requirements for marking and documentation are now in Clause 7. However, Clause 7 does not contain all the marking and documentation requirements. A few are so closely linked to other safety requirements that to separate them from their associated technical requirements seemed impractical. An example is the requirements for an emergency stopping device in subclause 9.2.4. In addition to characteristics such as proximity to the operator, the actuator must be colored red and marked with the word “STOP” or the symbol shown to the right.



However, it is recognized that the people who write the accompanying documents or design packaging and labeling for medical electrical equipment are often in different parts of the manufacturing organization than the engineers responsible for the design of the equipment. To assist those responsible for developing markings and accompanying documents, an informative annex (Annex C) has been added listing the subclauses outside of Clause 7 that contain marking and labeling requirements.

The requirements dealing with protection against various hazards begins with Clause 8, *Protection against electrical hazards from medical electrical equipment*. This material corresponds roughly to that contained in Section Three of the second edition. To simplify the structure of the document and reduce the jumping around between different sections, the electrical construction requirements from Section Ten were also moved into Clause 8. Table I maps the sections in the second edition of IEC 60601-1 to the clauses where that subject is covered in the third edition.

Because the use of flammable anesthetics is on the decline, the material in Section Six was changed to recommendations in an informative annex. While agreeing with placing the material in an annex, several IEC National Committees indicated a strong preference for maintaining this material as normative requirements. The requirements for equipment intended to be used in areas where flammable anesthetics or flammable agents for disinfection or skin cleaning are in use are located in Annex G of the third edition.

#### Mapping between the second and third editions

To assist users of IEC 60601-1 to trace requirements between the third edition and their sources in the documents that form the basis of the third edition, principally the second edition as amended, the secretariat of Subcommittee 62A has developed a technical report, IEC/TR 62348, *Mapping between the clauses of the third edition of IEC 60601-1 and the 1988 edition as amended*. This technical report is intended to be used by:

- those who must align standards based on the second edition of IEC 60601-1 with the third edition;
- manufacturers of medical electrical equipment or medical electrical systems; and
- health care regulatory authorities, test houses and

Section edition section	Third edition clause
Section One – General	Clauses 1 – 7
Section Two – Environmental conditions	Clause 4
Section Three – Protection against electrical shock hazards	Clause 8
Section Four – Protection against mechanical hazards	Clause 9
Section Five – Protection against hazards from unwanted or excessive radiation	Clause 10
Section Six – Protection against hazards of ignition of flammable anesthetic mixtures	Annex G
Section Seven – Protection against excessive temperature and other hazards	Clause 11
Section Eight – Accuracy of operating data and protection against hazardous output	Clause 12
Section Nine – Abnormal operation and fault conditions; environmental tests	Clause 13
Section Ten – Construction requirements	Clause 15

TABLE I  
MAPPING OF SECTIONS IN THE SECOND EDITION OF IEC 60601-1 TO  
THIRD EDITION CLAUSES

other organizations responsible for implementing standards for medical electrical equipment and medical electrical systems.

Table II contains an example from IEC 62348 that illustrates the mapping of elements in the second edition to where the requirements can be found in the third edition. IEC 62348 also contains tables that map from the third edition clauses back to the source documents.

#### Role of collateral standards in the third edition

Another issue that was hotly debated during the development of the third edition was the role of the collateral standards in the IEC 60601 family. The first collateral standard in the IEC 60601 family was developed after the second edition of IEC 60601-1 was published. Amendment 2 to the second edition added subclause 1.5, which described

Continued on Page 30

IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	Title	Clause	Title
19.3	“Allowable values”	8.7.3	Allowable values
19.3 a)	“a) The allowable values of the continuous...”	8.7.3 b)	
19.3 b)	“b) For frequencies above...” [first paragraph, modified]	8.7.3 a)	
19.3 b)	“However, the results...” [second paragraph]	8.7.3 e)	
19.3 c)	[not used, deleted]		
19.3 d)	[not used, deleted]		
19.3 e)	[not used, deleted]		
19.4	“Tests”	8.7.4	Measurements
19.4 a)	“a) General”	8.7.4.1	General
19.4 a) 1)	“1) The earth leakage current...”	8.4.7.1 a)	
19.4 a) 2)	“2) Equipment is connected...”	8.7.1 b)	
19.4 a) 3)	“3) Three-phase equipment which...” [deleted]		
19.4 a) 4)	“4) Where examination of...”	8.7.4.1 b)	

TABLE II  
EXAMPLE MAPPING BETWEEN THE ELEMENTS OF THE SECOND EDITION OF IEC 60601-1 AS AMENDED AND IEC 60601-1:2005

the kind of requirements that would be contained in a collateral standard and the relationship of the collaterals to particular standards. However, it was ambiguous with respect to whether or not equipment must comply with any relevant collateral standards before it could be considered to comply with IEC 60601-1. Opinion on the question seemed to be fairly evenly divided. In 2003, the subcommittee formally considered this question and decided that for the third edition a collateral standard becomes normative at the date of its publication and shall be applied, when applicable, with the general standard. In effect, this approach allows for an unlimited number of amendments to add new general requirements to IEC 60601-1 because each new collateral standard becomes a normative part of IEC 60601-1 when published.

Part of the agreement reached in 2003 included a plan for the transition of those collateral standards that were developed for the second edition. Those collateral standards would only become normative once a version structurally aligned to the third edition of IEC 60601-1 is published. At the 2005 meeting of the subcommittees, the National Committee members agreed to the secretariat’s plan for circulating the three existing collateral standards under the jurisdiction of Subcommittee 62A for a five-month ballot once the third edition is approved for publication. One other collateral standard, IEC 60601-1-3, *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*, is the responsibility of Subcommittee 62B. This document is already undergoing a technical revision and will be published as a third-edition collateral in due course.

The subcommittee has provided two important pieces of guidance as notes to subclause 1.3. Note 1 states that manufacturers should be able to independently assess compliance with any collateral standard. For example, manufacturers often use different assessment organizations (test houses) to evaluate the general safety requirements in IEC 60601-1 and the safety requirements for equipment with respect to electromagnetic phenomena in IEC 60601-1-2, *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests*. The subcommittee did not intend to turn this into a serial process where compliance with the applicable collaterals had to be demonstrated before compliance with the general standard could be assessed. Rather, the intent was to make clear that an unqualified claim of compliance with the IEC 60601-1 meant that the equipment not only complied with all the relevant requirements in the general standard but also all the relevant requirements in any applicable collaterals. This approach is consistent with the view that the requirements in a collateral standard are just as much a part of the general standard as are any of the requirements physically present in IEC 60601-1.

Note 2 in subclause 1.3 contains a recommendation that when declaring compliance with IEC 60601-1, the declarer should specifically list the collateral standards that have been applied. This will allow the reader of the declaration to understand which collateral standards were included in the evaluation. This list will take on greater significance as new collateral standards are published. Having a new collateral standard is essentially equivalent to having a major amendment to the general standard. However, the date associated with the general standard will not change so the reader will not be able to determine which collateral standards were in force at the time that compliance was assessed simply from the date of the general standard. Including a list will establish the exact version of the general standard used for determining compliance.

The role of the collateral standards as normative parts of the general standard was reinforced by a decision taken earlier in the project to incorporate the requirements of two existing collaterals into IEC 60601-1. The requirements from the first collateral, IEC 60601-1-1, *Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems*, covering medical electrical systems have been incorporated as Clause 16 of the third edition. The fourth collateral standard, IEC 60601-1-4, *Medical electrical*

equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems, covering programmable medical electrical systems (PEMS), has also been incorporated into Clause 14 of the third edition. IEC 60601-1-4 was the first standard in the IEC 60601 family to make extensive use of a risk management process. Now that a full risk management process complying with ISO 14971, *Medical devices — Application of risk management to medical devices*, is required by the general standard, many of the requirements in IEC 60601-1-4 are redundant.

ISO 14971 is the result of a joint development project between Subcommittee 62A and ISO Technical Committee 210. ISO 14971 was structured to address all the needs of the IEC 60601 family for a risk management process. Once the risk management process requirements were removed from IEC 60601-1-4, what remained were a relatively small number of requirements specifically applicable to Programmable Electrical Medical Systems (PEMS). These requirements have been placed in Clause 14. The intent was that a PEMS which complied with IEC 60601-1-4 will also comply with Clause 14 of the third edition without alteration. However, there is one subclause in Clause 14 of the third edition that is not in IEC 60601-1-4. That subclause deals with PEMS that are intended to be connected to other equipment through any means to transmit or received information. In IEC 60601-1, this is referred to as a “network/data coupling.” Subclause 14.13 requires the manufacturer of a PEMS that includes a network/data coupling to incorporate certain information in the technical description to assist the user of the equipment in managing the risks that can arise from connecting the equipment to things that are outside the control of the PEMS manufacturer.

Table III lists the collateral standards that have been published or are in development and their disposition once the third edition is published.

*Relationship to particular standards in the IEC 60601 family*

In the IEC 60601 family, general and collateral standards form the base on which the particular, or part 2, standards are built. Although often shown below the general and collateral standards in an apparent hierarchy (see Figure 1), they are in reality superior to the general and collateral standards. The particular standards determine which of the requirements of the general and collateral standards are applicable to the equipment within their scope. A particular standard may modify, replace or delete requirements in the general and collateral standards and may add other safety requirements. A requirement in a particular standard always takes priority over a requirement in either the general or a collateral standard.

Particular standards will also play a significant role in identifying the “essential performance” associated with the equipment within their scope. The concept of essential performance will be covered in more detail later.

*Relationship to basic safety standards*

The final elements of the IEC 60601 family are the basic safety standards that are incorporated by reference. IEC 60601-1 makes normative reference to some 58 IEC and ISO standards either in whole or in part. These standards encompass aspects as diverse as the methods of measuring the water tightness of enclosures to requirements for power transformers to requirements for human exposure to hand-

Collateral Standard	Subject/Status
IEC 60601-1-1	[obsolete—incorporated into the third edition]
IEC 60601-1-2	Electromagnetic compatibility
IEC 60601-1-3	X-ray – radiation protection
IEC 60601-1-4	[obsolete—incorporated into the third edition]
IEC 60601-1-5	[obsolete]
IEC 60601-1-6	Usability
IEC 60601-1-7	[obsolete]
IEC 60601-1-8	Alarm systems
IEC 60601-1-9	Requirements for environmentally conscious design <sup>a</sup>
IEC 60601-1-10	Physiologic closed-loop controllers <sup>a</sup>
IEC 60601-1-11	Medical electrical equipment and systems used in home care applications <sup>a</sup>
<sup>a</sup> under development.	

TABLE III  
COLLATERAL STANDARDS IN THE IEC 60601-1 FAMILY

transmitted vibration. Increased harmonization with basic safety standards was one of the key objectives set out in IEC 60513 for the third edition project. Substantial progress was also made in aligning requirements with those for IT equipment when patient safety was not directly affected. That will also be discussed in more detail later.

#### IV. Role of Risk Management in the third Edition

Seemingly, the most far-reaching change in the third edition is the requirement for the manufacturer of medical electrical equipment or medical electrical systems to have a formal risk management system in place. There are several reasons of the integration of a formal risk management process into the third edition of IEC 60601-1. For one, any standard represents the state of technology at a point in time. Applying a risk based approach enables the manufacturer to take advantage of evolving technology while continuing to improve the safety of their devices. The manufacturer need not be wedded to the risk control measures in the standard if they can show that newer approaches result in the same or less residual risk.

Many of the requirements in IEC 60601-1 are designed to reduce a risk to a point that the residual risk is considered by the stakeholders to be broadly acceptable regardless of

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the type of equipment or its application. In other cases, an uncontrolled risk may be judged to be generally unacceptable but it is recognized that it need not be reduced to the same absolute level in every application. The risk management process provides the manufacturer with a tool for “tailoring” the standard to the needs of a particular intended use.

The introduction of formal risk management also recognizes that compliance with IEC 60601-1 alone may not be enough to ensure a safe device. Compliance with relevant part 2 standards helps but even they may not be sufficient for every intended use.

Actually, manufacturers have been doing risk management all along even if they have not recognized it as such. After all, what is a safety standard other than a collection of tried-and-true risk control measures that reduce the risk associated with a particular hazard or hazardous situation to an acceptable level? In the first and second editions, the architects of the standard did the risk management for the user. Hazards were identified, risk control measures specified, and risk acceptability criteria were established by the authors as prescribed pass/fail values. The IEC 60601-1 requirements for leakage current are a prime example. Meeting the leakage current requirements does not eliminate the risk of being harmed by an electric shock. However, it does reduce the probability of occurrence of harm to a level that is considered by the stakeholder community to be generally acceptable. Manufacturers have always had to identify and manage the risks arising from their equipment that were not covered by the general standard. Particular standards help by identifying particular hazards associated with specific types of equipment and provide risk control measures to manage those risks. However, even particular standards may not cover every aspect of a particular design. The manufacturers still had to understand their equipment, identify relevant hazards, and develop their own risk control measures when the available standards were not adequate or applicable to their particular needs.

What is new is the requirement for the manufacturer to have a formal and documented risk management process that conforms to ISO 14971. ISO 14971 describes a total life cycle approach that does not end when design and testing is complete. While it does not specify acceptable risk, it provides a framework for managing risks that is fully auditable, and one that can be integrated into the manufacturer’s quality management system, although this is not required by either ISO 14971 or IEC 60601-1.

ISO 14971 specifies three key documentation elements:

- The *risk management plan* is a comprehensive plan for how the risk management activities (risk analysis, risk evaluation, risk control, etc.) are going to be carried out for a particular equipment or system including the criteria that will be used to judge if a specific risk is acceptable or not. While the manufacturer establishes the criteria, they are by no means arbitrary. The criteria are determined up front in accordance with a policy established by the manufacturer’s top management. The policy must ensure that the criteria are based upon applicable national or regional regulations and relevant international standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns.
- The *risk management report* is a report created just

prior to the release of the equipment or system to commercial distribution. This report summarizes a review of the risk management process to this point and serves as a “completeness check” to ensure that all aspects of the risk management plan have been implemented, the overall residual risk of the equipment or system is acceptable, and that appropriate mechanisms are in place for collecting and processing production and post-production information.

- The *risk management file* is a term used throughout ISO 14971 and IEC 60601-1 to describe those design, testing and other quality records that are created as a result of applying risk management to the equipment or system. The risk management file need not physically contain all the records and other documents; however, it should contain at least references or pointers to all required documentation. In IEC 60601-1, all safety related information, including the manufacturer’s calculations, test results, etc., are considered to be a part of the risk management file.

IEC 60601-1 makes use of the risk management process in several ways:

- It provides a formal and documented mechanism for identifying and dealing with risks that are not covered by the standard. This approach recognizes that the general standard and possibly even a particular standard might not adequately control all the risks associated with a specific design or application.
- It is used in cases where the architects of the general standard have identified that without some risk control an unacceptable risk is likely to occur, but IEC 60601-1 is unable to specify any detailed requirements to manage those risks. In the second edition, these areas were highlighted by saying “no general requirement.” In the third edition, “no general requirement” has been replaced with a requirement that these areas be address in the risk management process. As with the second edition, it is anticipated that when applicable the part 2 standards will specify particular requirements in these areas.
- It is used to determine when specific requirements are to be applied. An example, which is discussed later, is deciding which accessible parts, while not being applied parts, need to be subjected to the requirements for applied parts.
- It is used to determine appropriate test parameters. For example, the spillage test in subclause 11.6.3 uses risk assessment to determine the liquid type, volume, duration, and location of the spill.
- It is used to when the general standard is not able to specify the pass/fail criteria for a particular test. An example is found in subclause 15.3.6 dealing with enclosures of molded or formed thermoplastic. This subclause specifies a thermal cycling test for the enclosure with specific temperatures and duration. However, in one instance small cracks or deformation of the enclosure might not result in anyone being exposed to a hazard, and therefore, the cracks or deformation are acceptable from a safety point of view. In another instance, the same results might result in an unacceptable enclosure



leakage current and consequently would constitute a failure. The manufacturer uses risk management to make and document this determination.

It must also be noted that there is a reciprocal relationship between the third edition of IEC 60601-1 and ISO 14971. While IEC 60601-1 requires the application of risk management, ISO 14971 also explicitly recognizes that when devices comply with the requirements of relevant safety standards, the risk addressed by those requirements should be considered acceptable. This point is reinforced in subclause 4.2 of IEC 60601-1, which states:

“Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular risks, and these requirements are complied with, the RESIDUAL RISKS addressed by these requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.”

## V. Introduction of Essential Performance

A second and perhaps even more far-reaching change in the third edition is the introduction of essential performance. Essential performance is defined as the “performance necessary to achieve freedom from unacceptable risk.” Subclause 4.3 of the general standard requires the manufacturer of medical electrical equipment or medical electrical systems to:

- identify which functions of the equipment or system are essential performance; and
- verify by inspection or functional test that these functions are present following those tests that specify that both basic safety and essential performance are to be maintained.

While essential performance is defined in terms of achieving freedom from unacceptable risk, it is most easily understood by considering when the loss or degradation of a performance aspect of the medical electrical equipment or system renders the equipment or system no longer fit for its intended use. If that loss or degradation of performance results in an unacceptable risk, then the performance aspect would be considered essential performance within the context of a particular intended use. Understanding the intended use is important because it determines the criticality of the particular performance aspect. Take the often discussed case of the ultrasound imaging equipment. Is the ability to produce a useful image essential performance? The answer depends on what the image is intended to be used for. If the intended use is a routine diagnostic procedure, then the failure to produce a usable image is annoying, perhaps even seriously inconvenient, but there is no significant harm and consequently no essential performance. If the intended use is to produce an image where the need for a correct and timely diagnosis is critical to the patient receiving proper care, then a failure to perform might lead directly to significant harm. In the latter case, the ability to produce a useful image could be considered essential performance.

The manufacturer is responsible and accountable for determining if the absence or degradation of any particular performance aspect of their medical electrical equipment or system constitutes an unacceptable risk. The manufacturer uses the risk management process to make this determination. The manufacturer has to decide if a particular risk is acceptable considering factors such as:

- applicable standards that specify requirements

which, if implemented, will indicate achievement of acceptability concerning particular kinds of medical devices or particular risks;

- the levels of risk evident from similar devices already in use; and
- clinical study data, especially for new technology or new intended uses;

all the while taking into account the current state of technology and practice existing at the time of design.

Although IEC 60601-1 defines the term “essential performance” and requires the manufacturer to identify the functions that constitute essential performance, there are actually very few essential performance requirements in the general standard. That is because essential performance is very difficult to identify in the general case. A function that may be essential in one type of equipment intended for a particular application may be absent or degraded in another situation without causing an unacceptable risk. The manufacturer has to examine each aspect of the equipment or systems in the context of its intended use and determine which performance features are essential to the safety—the freedom from unacceptable risk—of the equipment or systems.

It is anticipated that the part 2 standards will play a leading role in the identification of essential performance for particular equipment or systems.

One example of how essential performance is used in IEC 60601-1 is found in subclause 9.5.5.1 on protection of defibrillation-proof applied parts. In part, that subclause states:

“Following exposure to the defibrillation voltage, and any necessary recovery time stated in the ACCOMPANYING DOCUMENTS, the ME EQUIPMENT shall comply with relevant requirements of this standard and shall continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.”

It is worthwhile to note that the parallel requirement in the second edition of IEC 60601-1 (subclause 17 h)) requires that:

“After any necessary time of recovery, stated in the ACCOMPANYING DOCUMENTS, the EQUIPMENT shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.”

On the surface, this appears to be a loosening of the requirement. The second edition requires the equipment return to performing its “intended function” after the recovery time as stated in the accompanying documents. The third edition requires the equipment to maintain basic safety and provide essential performance. This approach is consistent with the roadmap laid out in IEC 60513. IEC 60601-1 is a safety standard and deals with aspects of the equipment or system that impact on its safe use. Other aspects, which may be very important to both the use and the manufacturer, are outside the scope of IEC 60601-1.

The concept of essential performance is not entirely new to IEC 60601. The second edition of IEC 60601-1-2 published in 2001 introduced the concept of essential performance as a way for manufacturers to restrict immunity testing. Only those functions of the equipment or system that the manufacturer determined to be essential performance through a risk analysis were required to meet the immunity requirements of this collateral standard. If the manufacturer chooses not to identify the essential performance of the equipment, then all functions of the equipment or system had to be tested to the immunity requirements of IEC 60601-

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1-2. The third edition of IEC 60601-1, in essence, broadens that concept to cover many more aspects of the equipment or system.

## VI. Rationalizing the Structure of the Third Edition

When Subcommittee 62A set out to revise IEC 60601-1, one of the first tasks was to rationalize the structure of the standard. This was no mean task because many requirements, particularly those for electrical safety, were spread through several sections of the document. It was also not without a certain amount of controversy. There was a substantial investment in time and energy in deciphering the second edition. Many experts in the field could quote “chapter and verse” from the bible and not a few organizations had built references to specific clauses and subclauses into their internal documentation. After considering all the arguments, the subcommittee decided to move ahead with restructuring the standard along the lines suggested by Germany. The overall structure of the third edition was described earlier in this article. In the remainder of this article, I will outline what I see as some of the key technical differences between the third edition and its predecessor documents. I will generally discuss items in the order that they appear in the standard beginning with Clause 4.

### *General requirements, requirements for testing, and classification*

Clause 4 establishes the general requirements that are applicable to all covered equipment and systems. It contains the requirements for risk management and identification of essential performance already discussed. In addition, subclause 4.4 requires the manufacturer to document in the risk management file the expected service life—maximum period of useful life as defined by the manufacturer—for the equipment or system. This is necessary because other requirements in the standard specify that particular risks remain acceptable during the expected service life of the equipment or system. For example, see subclause 9.2.2 on tensile safety factor.

Subclause 4.5 deals with equivalent safety. This is an expansion of the alternative forms of construction allowance found in subclause 3.4 of the second edition. However, with the introduction of risk management there is a mechanism in the standard for demonstrating that an equivalent degree of safety is obtained.

Subclause 4.6 requires the manufacturer to use the risk management process to identify parts of the equipment or system that fall outside the definition of an applied part, but should be subject to the requirements for an applied part. These would be parts that unintentionally come into contact with an unconscious, anesthetized or incapacitated patient. These parts can present the same risk as a part that necessarily has to contact the patient. This change allowed for a simplification of the definition to restrict an applied part to only those parts of the equipment or system that in normal use must come in physical contact with the patient for the equipment or system to perform its function. A good example is ECG patient leads. These are not applied parts because it is not necessary for them to come into contact with the patient for an ECG monitor to perform its function. However, a simple risk analysis will show that these leads will often be in contact with the patient’s skin. Therefore, on the basis of this analysis, the ECG leads would need to

meet the same requirements as an applied part. The one exception is the requirement for marking of an applied part in subclause 7.2.10. As part of the rationale for the definition of applied parts, Annex A contains an extensive discussion of the characteristics of applied parts and the identification of applied parts and other parts that need to be treated as applied parts because of the probability that they will come into contact with the patient.

Subclause 4.9 deals with the use of components with high-integrity characteristics. These are components that are to be used where a fault in the components could cause an unacceptable risk. Components with high-integrity characteristics are those that can be demonstrated through testing or supplier certification to be fault-free in relation to the safety requirement of IEC 60601-1 during the expected service life of the equipment. For example, in the second edition, double and reinforced insulation are considered to be fault-free with respect to electrical breakdown.

Clause 5 deals with general testing requirements and is largely unchanged from the second edition. The process for identifying applied parts and accessible parts has been moved from Clause 16 of the second edition to subclause 5.9.

Clause 6 covers classification of equipment and systems and is largely unchanged from the second edition.

### *Markings and accompanying documents*

Clause 7 covers most of the requirements for marking and accompanying documents for equipment. Some additional marking and documentation requirements for systems are included in Clause 16. As mentioned earlier, an informative annex (Annex C) has been added listing the subclauses outside of Clause 7 that contain marking and labeling requirements. While the clause has been reorganized to improve readability, the requirements are not significantly different from those in Clause 6 of the second edition. However, as much of the required material constitutes “information for safety,” there is a new requirement that a usability engineering process be applied to the implementation of these requirements.

### *Electrical safety*

Clause 8 has been extensively restructured to bring together in one section the requirements relating to electrical safety. Most of the electrical requirements in Section 10 of the second edition including the requirements for creepage distances and air clearances have been moved into Clause 8. The mains transformer requirements remain in Clause 15 dealing with construction requirements because they relate to both electrical and thermal safety.

Following one of the principles established in IEC 60513, the requirements were reviewed to align them with basic IEC safety standards, such as IEC 60664-1, *Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests*, where possible.

As mentioned earlier, the concept of applied parts has been revised and simplified. The manufacturer uses risk management to identify parts of the equipment or system that fall outside the definition of an applied part but should be subject to the requirements for an applied part.

Another principle in IEC 60513 was to increase alignment with the general standard for IT equipment, IEC 60950-1. The reasons for improved alignment seem fairly obvious: increasingly, IT equipment and components are being integrated into medical electrical equipment or combined with medical electrical equipment to create medical electrical

systems. In the first and second editions of IEC 60601-1, the same electrical safety requirements were applied to operators and patients even though their safety concerns are different. The requirements in the two standards were enough different that IT equipment or components could not be used without additional testing and certification. This meant that medical grade power supplies, for example, were often somewhat larger and more expensive than comparable supplies produced in quantity for the IT industry. The alignment of requirements such as creepage distances and air clearances when used as a means for protecting the operator should make some components certified to IEC 60950-1 available for use in medical applications without further testing or certification. In addition, these changes recognize unofficial test house agreements to accept reduced spacings without any justification by the standard.

The spacing requirements in the second edition of IEC 60601-1 did not take into account factors such as voltage transients, pollution classification, material tracking indices and the effects of altitude, nor did the second edition address spaces filled with solid insulation. IEC 60950-1 has incorporated most of these concepts from basic IEC safety standards. Taking these factors into account should provide manufacturers more design flexibility, reduce equipment size and allow for more use of readily available IT-certified

components.

To take full advantage of the approach used in IEC 60950-1, a new concept was introduced into the third edition—means of protection. Means of protection is defined as any “means for reducing the risk due to electrical shock in accordance with the requirements of this standard.” A means of protection includes insulation, air clearances, creepage distances, impedances and protective earth connections. Means of protection is subdivided into means of *operator* protection (MOOPs) and means of *patient* protection (MOPPs). A MOOP is defined as any “means of protection for reducing the risk due to electric shock to persons other than the patient.” A MOPP is defined as any “means of protection for reducing the risk due to electric shock to the patient.” For example, solid insulation forming a means of patient protection must withstand a test voltage of 1.5 times that of solid insulation that forms a means of operator protection at any given working voltage.

However, the manufacturer has options for insulation coordination. Those choices are illustrated in Figure A.12 of third edition, which is reproduced in Figure 2. For applied parts and parts subject to the requirements for applied parts, the requirements of IEC 60601-1 are used. The requirements in the third edition are the same as those in the second edition. If the means of protection is a MOOP, then the

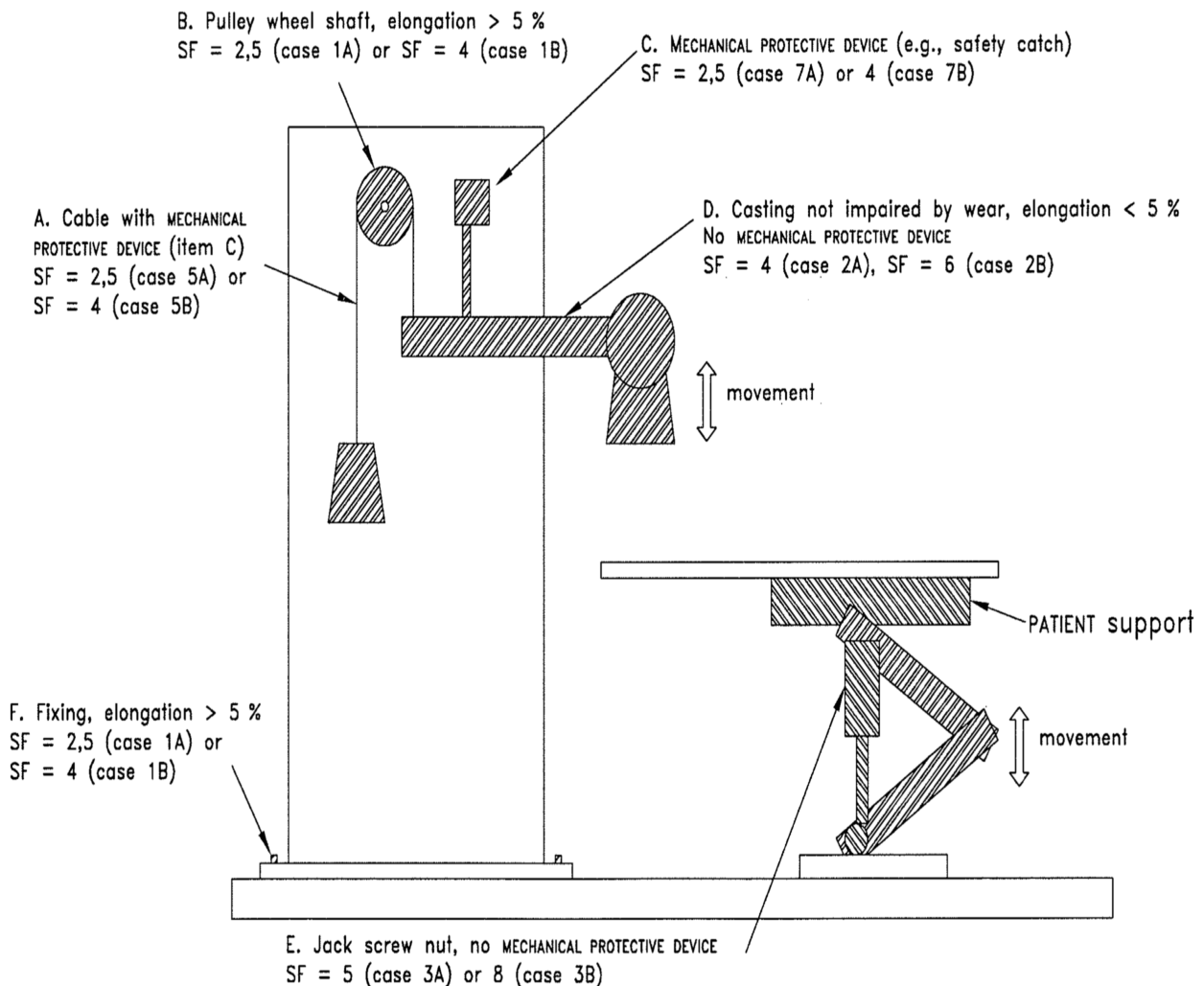


Fig. 2. Identification of means of patient protection and means of operator protection

Continued on Page 36

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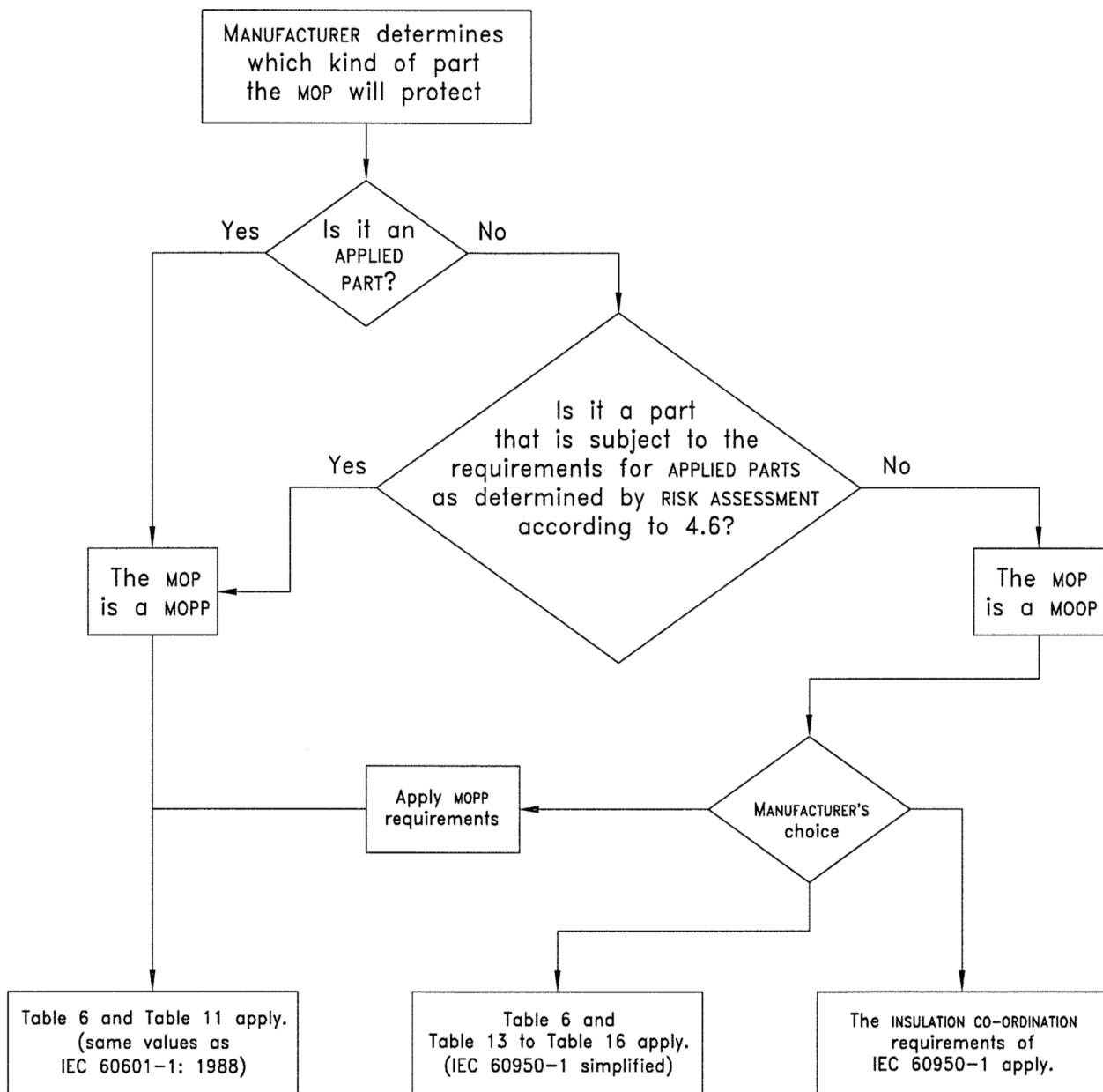
manufacturer has choices. The requirements for MOPPs can be applied, which is the equivalent of the second edition. Alternatively, the manufacturer can choose to apply the requirements in Tables 13 to 16, which are taken from IEC 60950-1 and are based on IEC 60664-1 and certain assumptions about possible overvoltages in mains and other circuits and the frequency of occurrence of various levels of overvoltage. Finally, the manufacturer can apply the insulation coordination scheme described in IEC 60950-1. This last option is probably most attractive to manufacturers who already have experience with designing IT equipment

but others may also find it useful as it provides the most flexibility.

*Mechanical safety*

Most of the mechanical requirements have been gathered into Clause 9. The mechanical requirements have been reorganized and substantially expanded. The clause is organized around specific mechanical hazards: crushing, shearing, cutting or severing, etc.

New requirements have been added for acoustic energy



“MOP” = MEANS OF PROTECTION  
 “MOPP” = MEANS OF PATIENT PROTECTION  
 “MOOP” = MEANS OF OPERATOR PROTECTION

*Fig. 3. Example of determining tensile safety factor*

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(noise) and for hand-transmitted vibration.

The requirements for tensile safety factors for patient support systems have been refined to reflect the possibility of employing a lower safety margin when all external forces to be expected are quantifiable and known accurately. This concept is illustrated in Figure A.17 of third edition, which is reproduced in Figure 3. In this figure, “case” refers to situations described in Table 21 of the third edition.

The mechanical strength of the enclosure to resist impacts, dropping and rough handling remain in the clause on equipment construction (Clause 15) because the enclosure provides protection against electrical and thermal as well as mechanical hazards.

#### *Protection against excessive radiation*

Clause 10 covers hazards from excessive radiation of all types. The requirements for X-radiation are substantially the same as the second edition. However, the requirements for X-radiation produced for diagnostic or therapeutic reasons have been moved to Clause 12. Requirements for lasers, light emitting diodes and infrared radiation produced by lasers and light emitting diodes are covered by a reference to IEC 60825-1, *Safety of laser products - Part 1: Equipment classification, requirements and user's guide*. The requirements for electromagnetic compatibility are moved to Clause 17. Finally, for other types of radiation, the “no general requirement” in the second edition has been replaced by a risk management requirement of the form, “The manufacturer shall address in the risk management process the risk associated with ....”

#### *Protection against excessive temperature and other hazards*

In Clause 11, the allowable temperature tables of the second edition have been simplified and the concept of duration of contact introduced for applied parts and parts likely to be touched. Based on the material and the maximum duration of contact, applied parts can exceed the 41 °C requirement of the second edition provided the clinical effects of the high temperature are justified in the risk management file and the maximum temperature disclosed in the instructions for use.

Clause 11 also contains enhanced fire safety requirements particularly in regard to equipment and systems used in conjunction with oxygen-rich environments.

#### *Accuracy of controls and protection against hazardous output*

Clause 12 contains requirements for the accuracy of controls and protection against hazardous output. The requirements for diagnostic X-ray equipment, radiotherapy equipment, other equipment producing diagnostic or therapeutic radiation, and equipment producing diagnostic or therapeutic acoustic pressure, have been moved into this clause. Clause 12 requires the manufacturer to address the risk associated with poor usability of the equipment or system utilizing the usability engineering process in IEC 60601-1-6, *Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability*. When applicable, this clause also requires the manufacturer to address the use of an alarm system as a means of risk control by applying the requirements in IEC 60601-1-8, *Medical electrical equipment - Part 1-8: General*

*requirements for safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*

#### *Single fault conditions*

Clause 13 deals with specific single fault conditions that, when applied one at a time, must not result in any of the hazardous situations described in the clause. These fault conditions are largely the same as those described in Clause 52 of the second edition although some of the tests have been moved to other parts of the standard. The tests for motor operated equipment and equipment with heating elements remains in this clause.

#### *Programmable medical electrical systems*

Programmable medical electrical systems (PEMS) are dealt with in Clause 14. This clause incorporates the requirements from IEC 60601-1-4. Many of the requirements in IEC 60601-1-4 were directed at providing a risk management framework for evaluating the process of developing a PEMS. In actuality, the risk management process introduced when IEC 60601-1-4 was published in 1996 was a basis for the first edition of ISO 14971. Now that risk management is required by the general standard, many of the requirements in IEC 60601-1-4 are redundant. Stripping these process requirements away leaves a core set of requirements for the PEMS development life-cycle and the additional elements for the PEMS that need to be considered as part of the risk management process.

An effort was made to not modify the PEMS requirements in any substantial way while incorporating them into the third edition. A process that satisfies the requirement of IEC 60601-1-4 should have no difficulty in complying with Clause 14. The only new requirement appears in subclause 14.13. This subclause specifies some additional documentation requirements for a PEMS that is intended to be connected to other equipment through any means to transmit or receive information to or from the other equipment.

Clause 14 deals with both the hardware and software aspects of the PEMS. It is long been recognized that more could be done to address the medical device software development life cycle. A new standard, IEC 62304, *Medical device software – Software life cycle process*, is being developed by IEC Subcommittee 62A in partnership with ISO Technical Committee 210. Published in 2006, this standard addresses some of the particular aspects of PEMS software not covered in Clause 14.

#### *Construction requirements*

Clause 15 contains the residue of the construction requirements found in Section 10 of the second edition. Principally these deal with the mechanical strength of enclosures, temperature and overload control devices, batteries, and mains transformers. These requirements are substantially the same as the second edition.

#### *Medical electrical systems*

Clause 16 contains a set of specific requirements for medical electrical systems. These requirements come from the second edition of IEC 60601-1-1. As with the PEMS clause, the intention was to incorporate these requirements without substantial alteration.

The one system requirement that is new in the third edition is found in subclause 16.6.3 and concerns total patient

leakage current. The second edition of IEC 60601-1 did not address the issue of equipment with multiple applied parts. As equipment with multiple applied parts became more common, the issue was addressed in a particular standard for multifunction patient monitoring equipment, IEC 60601-2-49:2001, *Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment*. Because multifunction patient monitoring equipment is not the only type of equipment that can have multiple applied parts, the basic leakage current requirements from IEC 60601-2-49 have been incorporated into Clause 8 of the third edition. A system may be made up of several pieces of medical electrical equipment, each with one or more applied parts. The system manufacturer must be concerned about the summing of leakage currents from each of those applied parts. Like the general standard, the second edition of IEC 60601-1-1 did not address this safety concern. Subclause 16.6.3 requires that the total patient leakage current for the system cannot exceed the limit specified in Clause 8 for a single piece of medical electrical equipment. However, the standard recognizes that for a system with many combinations and permutations, this may be very difficult to measure on the bench. The standard allows the total patient leakage current for a system to be measured at installation.

#### *Electromagnetic compatibility*

The final clause in the third edition of IEC 60601-1 is a short clause dealing with the safety of equipment and systems in the electromagnetic environment. This clause requires the manufacturer to manage the risks associated with the electromagnetic phenomena existing in locations where the equipment or system is intended to be operated (immunity) and the introduction by the equipment or system of electromagnetic phenomena that might degrade the performance of other equipment or systems (emissions). Both subjects are addressed in IEC 60601-1-2.

#### *The annexes*

The remainder of the document is made up of annexes, the first and largest being Annex A, *General guidance and rationale*. This annex has been greatly expanded and, in my opinion, is one of the most important parts of the document. Persons new to IEC 60601-1 and even the old hands may find it useful to read the rationale for a particular subclause before reading the subclause itself. Many of the requirements in IEC 60601-1 are relatively obvious to anyone at all familiar with medical devices. However, because IEC 60601-1 is a collection of risk control strategies, it is often useful to understand the hazards the architects of the third edition had in mind when constructing the requirement. This is particularly useful when considering equivalent safety under subclause 4.5.

## **VII. Conclusion**

Much has changed in the third edition yet much has remained the same. The “bible” remains focused on improving patient safety. While substantially reorganized, most of the requirements in the second edition remain with little real alteration. New requirements have been added to deal with both technological evolution and changes in the perceived state of the art in safety requirements. More options have been provided for dealing with construction requirements such as creepage distances and air clearances.

The major changes are in the recognition that safety standards are a part of risk management and require a risk management process to be properly applied. For medical electrical equipment and systems, the third edition also recognizes that safety is more than the basic safety covered in the second edition. Essential performance must also be addressed. This recognition is the springboard for much of the work that faces those involved with developing the part 2 standards in the IEC 60601 family over the next several years. I am sure that the process of codifying what is “essential” will result in many intense debates among the experts in the committees responsible for producing those standards.

Every journey begins with a single step. That first step was taken nearly thirty years ago when a group of dedicated and forward-thinking people gathered to form IEC Technical Committee 62 and write the first “bible.” The publication of the third edition is not the end of the journey but just another step along the path. Work on planning the first amendment is already underway with publication likely to occur early in the next decade.

#### ACKNOWLEDGMENT

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delegate to the International Standards Organization (ISO) working group on symbols, definitions, and nomenclature for medical devices; the ISO working group on fundamental standards for implantable products; the ISO/IEC joint working group on pacemakers; and the ISO/IEC joint working group on application of risk management to medical devices. He is active as an IEC observer in the work of the CEN/CENELEC Joint Working Group on Active Implantable Medical Devices that is developing European standards under the auspices of the European Union. He is currently serves as the Vice-chairman of the Association for the Advancement of Medical Instrumentation.

Mr. Sidebottom has spoken and written frequently on the subject of medical device labeling. He is the author of the book *International Labeling Requirements for Medical Devices, Medical Equipment, and Diagnostic Products*.

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<sup>1</sup> In vitro diagnostic equipment that does not fall within the definition of medical electrical equipment is covered by the IEC 61010 series. IEC 60601-1 also does not apply to the implantable parts of active implantable medical devices covered by the ISO 14708 series.

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## Online Communities Story

*“A professional society provides a forum for advances to be related, and for people to learn about them.”-Benjamin Richard Teare, Jr.*

When IEEE was founded, its members could easily get together for face-to-face, real time communication due to their location. But, as the membership of the Institute grew, efforts had to be made to increase the participation of those living in other parts of the country.

Additionally, as the scope of electrical engineering expanded, engineers became more specialized and sought to exchange information with others in the same specialties. It was this need to interact that led to the formation of the first Technical Committee in 1903.

Today, with the continuing growth in membership throughout the world, we must find new ways to provide that same level interaction regardless of location. Additionally, the IEEE recognizes other organizational and individual member needs such as:

- Ability for IEEE Members, Governance, Committees, and Staff to collaborate, synchronously or asynchronously, outside of live meetings and teleconferences
- Retain IEEE “corporate memory”
- Increase volunteerism and by making it easier for individuals to participate
- Accelerate the sharing and delivery of domain-specific knowledge for IEEE Members and Customers which can be utilized to accomplish their work-related tasks

Through the means of new technology, we can now bridge geographical boundaries and provide additional opportunities for IEEE Members, Volunteers, Staff, and Governance to communicate and collaborate through use of Online Communities.

An Online Community consists of a group of individuals that have a shared purpose or common interests that utilize online communication and collaboration tools to facilitate the accomplishment of their goals or to fill voids that may currently exist by relying solely on in-person or real-time interactions. Online Community Members are engaged in value-creating relationships with “anytime/anywhere” access to shared knowledge. Through the use of tools in the software platform, community members interact socially, which facilitates a sense of togetherness.

Some benefits of Online Communities are:

- Online collaboration and continued communication outside of in-person meetings and teleconferences.
- Networking opportunities
- Discussions on the latest technologies, vital issues, and IEEE activities
- Just-in time education for application on the job
- Access to technical experts and peers for question asking, advice, and problem-solving
- Peer review of work

At IEEE, the goal of online collaboration is to call forth the best that members have to offer one another and minimize all of the obstacles that we can in order for this exchange to occur.

IEEE delivers tools and methods for online collaboration so that each community can quickly focus on vital issues or projects at hand, operate in a cost-effective manner, enhance continuity of effort, clarify and gain consensus through dialogue, create synergistic interdependence with other IEEE constituencies and create valuable resources.

User Guide for IEEE Online Communities:

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To discuss Carl’s paper go to <https://www.ieeecommunities.org/emc-pstc?go=1306656>



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